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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,037	05/21/2007	Thomas Arnebrant	30986/42246	3658

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	**PAPER NUMBER**
1655	

MAIL DATE	DELIVERY MODE
09/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,037	ARNEBRANT ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment has been received and entered.

2. Claims 1-17 have been cancelled.

3. Claims 18-25 have been added and are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 18 is indefinite because it appear that the limitation that the adsorption is "at least 1.2 g/m^2" should be "1.2 $\underline{mg}/m^2$" instead.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 19, 21, 24, and 25 recite a broad range/limitation followed by several "preferable" ranges which are narrower statements of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 18-20, 22, 23, and 25 rejected under 35 U.S.C. 102(b) as being anticipated by Attstrom et al. (US Pat. No. 5,260,282).

This reference teaches a method of treating xerostomia using linseed extract which is freeze-dried (see column 1, lines 16-28, column 4, lines 20-23, Examples 1 and 3 and claims). The reference does not teach that the linseed extract has the adsorption values claimed by applicant. However, according to page 16 and the figure in applicant's specification, freeze-dried linseed extract exhibits the adsorption characteristics claimed. Thus, the linseed extract used in Attstrom inherently contains the adsorption characteristics required by the claims. Therefore, the method of treating xerostomia taught by Attstrom properly anticipates the claimed invention.

7. Claims 18-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Mullane et al. (WO 93/16707).

This reference teaches a method of treating xerostomia using linseed extract that is freeze-dried or spray-dried to a powder (see page 2, second paragraph, page 3, last paragraph and page 5, first paragraph). The reference does not teach that the linseed extract has the adsorption values claimed by applicant. However, according to page 16 and the figure in applicant's specification, freeze-dried and spray-dried linseed extracts exhibit the adsorption characteristics claimed. Thus, the linseed extracts used in O'Mullane inherently contain the adsorption characteristics required by the claims. Therefore, the method of treating xerostomia taught by O'Mullane properly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 18 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Mullane.

The teachings of this reference are discussed above. The reference teaches drying the linseed extract but does not specifically teach creating a composition with the water content claimed. The amount of water in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA

1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of dryness in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of water amount would have been obvious at the time of applicant's invention.

The reference does teach formulating the linseed extract into oral administration forms such as lozenges (see page 4) but does not specifically teach formulating the composition into tablets or capsules as claimed by applicant. These pharmaceutical forms are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant.

9. Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Attstrom in view of O'Mullane.

As discussed above, Attstrom teaches treating xerostomia using freeze-dried linseed extract. The reference does not teach spray-drying the extract. O'Mullane teaches that both freeze-drying and spray-drying were known in the art at the time of the invention to be useful in creating dried linseed extracts for treating xerostomia. Thus, an artisan of ordinary skill would reasonably expect that spray-drying could be substituted for freeze-drying in the creation of the extract used in Attstrom. This reasonable expectation of success would motivate the artisan to modify Attstrom to include spray-drying as taught by O'Mullane.

The references teach drying the linseed extract but do not specifically teach creating a composition with the water content claimed. The amount of water in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of dryness in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of water amount would have been obvious at the time of applicant's invention.

O'Mullane does teach formulating the linseed extract into oral administration forms such as lozenges (see page 4) but does not specifically teach formulating the composition into tablets or capsules as claimed by applicant. These pharmaceutical forms are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the references in the forms claimed by applicant.

The references do not teach that the linseed extract has the adsorption values claimed by applicant. However, according to page 16 and the figure in applicant's specification, freeze-dried and spray-dried linseed extracts exhibit the adsorption characteristics claimed. Thus, the

linseed extract made according to the combination of Attstrom and O'Mullane intrinsically contains the adsorption characteristics required by the claims. Therefore, the method of treating xerostomia taught by Attstrom and O'Mullane properly meets the claimed limitations.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Coe Hoffman
Primary Examiner
Art Unit 1655